### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	) MDL NO. 1456 ) Master File No. 01-CV-12257-PBS
THIS DOCUMENTS RELATES TO ALL ACTIONS	) Judge Patti B. Saris ) )

## THE TOGETHER RX DEFENDANTS' OPPOSITION TO MOTION TO INTERVENE IN THE IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION, MDL NO. 1456

The Together Rx Defendants<sup>1/</sup> hereby oppose the motion of Roberta S. Starks and Kimberly K. Hoover, as attorney-in-fact for her mother Jeanne F. Kennedy ("Proposed Intervenors") to intervene as plaintiffs in this action.<sup>2/</sup> Plaintiffs' claims and theories have been a moving target since day one, and the motion to intervene is merely a disguised effort to amend the pleadings yet again. In fact, the motion to intervene is a transparent, and futile, attempt to correct a fatal flaw brought to light by Together Rx Defendants' Motion to Dismiss. Because the Proposed Intervenors fail to allege, and will be unable to prove, a colorable claim against the

The Together Rx Defendants are comprised of Together Rx LLC ("Together Rx") and its member companies, Abbott Laboratories; AstraZeneca Pharmaceuticals LP; Aventis Pharmaceuticals Inc.; Bristol-Myers Squibb Company; SmithKline Beecham Corporation d/b/a GlaxoSmithKline; Janssen Pharmaceutical Products, L.P. and McNeil-OPC, Inc. (both affiliates of Johnson & Johnson); and Novartis Pharmaceuticals Corporation. The Amended Master Consolidated Complaint ("AMCC") and the Proposed AMCC filed with the Motion to Intervene allege that TAP Pharmaceutical Products, Inc. ("TAP") is a member of Together Rx, but that allegation is wrong, TAP is not a member of Together Rx.

The Motion to Intervene is ambiguous as to who are the moving parties. The opening of the motion is framed as a motion of the Proposed Intervenors. The motion closes, however, with a request not by the Proposed Intervenors, but by the existing "Plaintiffs" in the case, that the motion be granted.

Together Rx Defendants, and because it is time to put a stop to the constantly shifting ground of plaintiffs' pleadings, the motion to intervene should be denied.

#### **BACKGROUND**

Plaintiffs filed a Master Consolidated Class Action Complaint in September of 2002, which did not include any claims against Together Rx. Ten months later, in July of 2003, plaintiffs amended the complaint to add antitrust claims against Together Rx, a coalition of pharmaceutical companies that provide direct subsidies to low-income seniors on their purchases of their drugs, and the member pharmaceutical companies that underwrite those subsidies.

Straining to assert an antitrust claim, plaintiffs in the AMCC ("AMCC Plaintiffs") alleged that the Together Rx Defendants conspired to increase the mark-up between Wholesale Acquisition Costs ("WAC") and Average Wholesale Prices ("AWP") to a generally uniform level, AMCC at ¶589, notwithstanding that the effect of such a conspiracy would require the member pharmaceutical companies to pay more to subsidize discounts under the program. AMCC Plaintiffs further assert that this alleged conspiracy caused harm to Together Rx cardholders, insurance companies and health plans, AMCC at ¶589, even though none of the many AMCC Plaintiffs is a Together Rx cardholder.

The Together Rx Defendants moved to dismiss the AMCC.<sup>3/</sup> In addition to demonstrating the economic irrationality of the conspiracy alleged, the motion to dismiss exposed the fact that no plaintiff was a Together Rx member and, therefore, no plaintiff could have overpaid for drugs provided through the program even in the unlikely event that the alleged conspiracy were to have such an effect. *Id.* at 12. That motion is *sub judice*.

No doubt recognizing the weakness of their standing position, plaintiffs now trot out the Proposed Intervenors, who are alleged to be Together Rx cardholders. By this latest gambit, they seek once again to amend their complaint, notwithstanding the Court's admonition three months

<sup>&</sup>lt;sup>3/</sup> See The Together Rx Defendants' Motion to Dismiss Counts V,VI, VII, VIII, and X of The Amended Complaint, August 1, 2003.

ago that it is "... not allowing any amendments that dramatically add new claims" (Transcript of November 21, 2003 hearing at 46:5-10), a clear indication that further substantive alterations in the case are not appropriate.

Moreover, the Proposed Intervenors' claims rest on the same naked allegation of "conspiracy" as the AMCC, and therefore suffer from the same flaw: they do not, and cannot, include any factual allegations supporting the conclusory assertion of a conspiracy, because the alleged increase in the mark-up taken between WAC and AWP about which they complain was clearly the result of actions taken by First DataBank, an independent reporting agency, and not by the Together Rx Defendants. For example, as detailed below, at all relevant times, Together Rx member companies, GlaxoSmithKline ("GSK"), Bristol-Myers Squibb ("BMS"), AstraZeneca Pharmaceuticals LP ("AstraZeneca "), and Aventis Pharmaceuticals Inc. ("Aventis") have not reported AWPs. Nonetheless, without any direction from these companies, in 2002, First DataBank unilaterally increased the AWPs it publishes for their drugs. Although Together Rx companies Janssen Pharmaceutica Inc. ("Janssen") and Novartis Pharmaceuticals Corporation ("Novartis") do report suggested AWPs to industry publications, beginning in 2002, First DataBank took it upon itself to publish AWPs for those companies' products that were higher than the suggested AWPs reported by the companies. In 2002 (the year in which plaintiffs contend that the <u>Together Rx Defendants</u> conspired to increase the mark-up between WAC and AWP on drugs sold to Together Program enrollees) the AWPs published by First DataBank were higher than the AWPs published by other reporting agencies, such as Red Book, for many of the drugs at issue. In short, First DataBank, and not any of the Together Rx Defendants, is responsible for any increases in the mark-up between AWP and WAC cited by plaintiffs in the AMCC.

In light of the procedural history and background facts summarized above, and for the reasons set forth below, the motion to intervene should be denied.

#### **ARGUMENT**

## I. Plaintiffs' Attempt at a Back Door Amendment to the Amended Master Consolidated Class Action Complaint Should be Denied.

In an effort to control what would otherwise be an unwieldy and unmanageable litigation, this Court has required plaintiffs to allege a specific plaintiff who has purchased a specific drug from a specific company in order to state a claim. *See* Memorandum and Order dated May 13, 2003 at pp. 41-45. Moreover, having given plaintiffs several opportunities to correct the defects in their pleading, this Court has also made it clear that no more substantive amendments will be allowed. *See* Transcript of November 21, 2003 hearing at 46:5-10. Notwithstanding this clear direction from the Court, the AMCC does not include any named plaintiffs who are Together Rx cardholders that purchased drugs covered by the Together Rx card program, despite the fact that the AMCC Plaintiffs purport to bring claims on behalf of such Together Rx card members. As demonstrated by the Motion to Dismiss filed by the Together Rx Defendants, the AMCC Plaintiffs therefore lack standing to bring the antitrust claims asserted against the Together Rx Defendants.

Recognizing this fatal flaw, but faced with the Court's admonishment that no more substantive amendments will be allowed, plaintiffs have instead filed this Motion to Intervene, in a back door attempt to secure yet another opportunity to shift and modify their claims to correct fatal defects uncovered through briefing on a motion to dismiss. This Court should not allow plaintiffs to succeed in their attempt to amend repeatedly their complaint. If allowed, this motion will no doubt be the first of many in a line of motions to intervene that plaintiffs will seek to file each time another flaw in their claims is exposed. The magnitude of this case presents enough case management challenges without plaintiffs expanding or changing it at their whim through the mechanism of adding "intervening" plaintiffs who allegedly purchased drugs that plaintiffs claim are at issue in this case.

<sup>&</sup>lt;sup>4/</sup> See The Together Rx Defendants' Brief in Support of Their Motion to Dismiss Counts V, VI, VII, VIII, and X of the Amended Complaint ("Motion to Dismiss Brief") at p. 12.

In sum, Plaintiffs have had substantial time and opportunity to amend the AMCC. This attempt to do so yet again through a purported motion to intervene should be denied.

### II. The Motion to Intervene Should Be Denied Because Proposed Intervenors' Claims are Futile.

Because the motion to intervene is in essence a motion to amend the complaint, it should be subject to the standards of a motion to amend, including the requirement that it not be futile. See e.g. Richards v. Relentless, Inc., 341 F.3d 35, 43 (1st Cir. 2003). It does not meet such standards. First, intervention is futile because the Proposed Intervenors' claims are subject to dismissal for the same reasons that the AMCC Plaintiffs' claims against the Together Rx Defendants should be dismissed. Second, intervention is futile because plaintiffs have pled no factual support for the conclusory assertion of "conspiracy" – as if that word was a talisman behind which no peeking is permitted – and, because First DataBank rather than the Together Rx Defendants modified the mark-up between WAC and AWP, plaintiffs can never plead such a basis as none exists.

### A. Proposed Intervenors' Claims are Futile Because They Fail as a Matter of Law.

As shown in the Together Rx Defendants' Brief in Support of Their Motion to Dismiss, it makes no economic sense for the Together Rx Defendants to have conspired to accomplish the allegedly parallel behavior of increasing the mark-up between their WACs and their AWPs by increasing AWPs, when they do not bill or collect "AWP." With respect to Together Rx card transactions – that is, the subsidization by the Together Rx member company of a consumer's purchase of that member company's drug at the pharmacy counter – there is clearly no economic incentive for a Together Rx company to conspire to raise its AWPs. In such a transaction, the

<sup>&</sup>lt;sup>5</sup>/ It is axiomatic that intervention should not be allowed if it does not allege a colorable claim. See e.g. Rhode Island Federation of Teachers, AFL-CIO v. Norberg, 630 F.2d 850, 855 (1st Cir. 1980) ("intervention under [Fed. R. Civ. P.] 24 is conditioned by the Rule 24(c) requirement that the intervenor state a well-pleaded claim or defense to the action").

Together Rx member company subsidizes the consumer's purchase in an amount represented by the difference between the pharmacy's sales price for the drug and the amount paid by the Together Rx cardholder. AMCC at ¶585. Depending upon the type of subsidy involved, increasing AWP would either plainly harm the Together Rx member company by requiring it to pay higher subsidies to the pharmacy or, at most, provide the Together member company no benefit at all. See Motion to Dismiss Brief at pp. 9-11.

In their Opposition to the Together Rx Defendants' Motion to Dismiss, plaintiffs in effect conceded that Together Rx cardholders could not be harmed by the alleged conspiratorial increases in AWP, but they insisted that purchasers of the same drugs *outside* the Together Card Program could be and were. <sup>6/</sup> In their motion to dismiss, the Together Rx Defendants showed that this allegation made no economic sense, either. Because the Together Rx Defendants do not bill or collect AWP, increasing the mark-up by increasing AWPs could not increase the revenue they got from any sale. Nor could increasing the WAC-to-AWP mark-up to a uniform level increase the number of prescriptions written for their products (as compared to competitors' products), so that it would make no sense to conspire to achieve such a uniform mark-up.

In sum, a complaint that alleges a conspiracy to engage in parallel behavior that it would make no economic sense to conspire to achieve does not state a claim. Because the Proposed Intervenors' claims are the same as the existing claims, for the same reasons that the Together Rx Defendants' motion to dismiss should be granted, the Proposed Intervenors' intervention would be futile and should therefore be denied.

Orugs, the Together Rx Defendants conspired to hurt the **broader** public of prescription drug end payors (such as self-insured employers, health plans and consumers) . . . An increase in AWP directly results in higher reimbursement prices to Plaintiffs and Class members for Together Card Drugs purchased **outside of** the Together Card Program." **See** Plaintiffs' Memorandum of Law in Opposition to the Together Rx Defendants' Motion to Dismiss at p. 13 (emphasis in original).

# B. Intervention Is Futile Because The Alleged Parallel Movements in AWP Resulted from the Unilateral Conduct of An Industry Pricing Publisher, Not From the Together Rx Defendants.

The Proposed Intervenors' motion is also futile because they do not, and cannot, offer any factual support for the central allegation in the AMCC relating to the Together Rx program, *i.e.*, the claim that, in 2002, the Together Rx Defendants conspired to increase the mark-up between the WAC and the AWP of drugs sold to individuals enrolled in the Together Program from 20% to 25%. In fact, as demonstrated in the attached affidavits, any published changes in the WAC/AWP mark-up were made by an industry pricing publication without direction or input from, and in many instances contrary to information provided to the publication by, each of the Together Rx member companies.

Briefly, the AMCC and new Proposed AMCC both include a chart which purports to establish that the mark-up between WAC and AWP of certain Together Rx members' drugs uniformly increased to 25% after the formation of the Together Rx Program in early 2002. Proposed AMCC at ¶ 591. Although the AMCC does not indicate the source of the AWP data depicted in the chart, it appears to come from First DataBank, one of the three leading drug price reporting publications – Red Book, First DataBank, and Medispan (the "Publications").

Fatal to the alleged conspiracy claim is the fact that the Together Rx member companies do not control the mark-up between published WAC and published AWP. Indeed, some Together Rx member companies do not even provide a suggested AWP to any of the Publications; the Publications unilaterally determine and list AWPs for those companies' products. In other cases, the Together Rx member companies reported or suggested AWPs to the Publications, but the Publications published AWPs entirely different from those suggested by the companies. In still other circumstances, different Publications listed different AWPs for the same product. For example:

AstraZeneca has not reported any AWP data to any of the Publications since before the creation of the Together Rx Program. See Affidavit of John Freeberry at ¶ 2, attached hereto as Exhibit 1. In 2002, without any direction or involvement from AstraZeneca, First DataBank increased the mark-up between WAC and AWP to 25% on all

AstraZeneca drugs on which First DataBank had previously been reporting a 20% mark-up. Id.

- Aventis has not reported AWP for its products since prior to August 2001. Affidavit of John Cervione at ¶ 2, attached hereto as <u>Exhibit 2</u>. Since August 2, 2001, Aventis has reported only WAC. *Id.* Even though Aventis has not reported AWP since before August 2001, the Publications continued to publish AWP for Aventis products. *Id.* at ¶ 3. Prior to 2002, First DataBank published prices indicating a 20% mark-up between WAC and AWP for many Aventis products. *Id.* Beginning in 2002, First DataBank changed the mark-ups on many Aventis products from 20% to 25%. *Id.* In March 2002, Aventis contacted its liaison at First DataBank, who informed Aventis that First DataBank intended to publish AWP prices that were 25% above WAC for all Aventis products. *Id.* Aventis did not suggest or direct First DataBank to publish an AWP for Aventis's products that was 125% of WAC. That unilateral decision was made by First DataBank without Aventis's involvement. *Id.*
- Since 1991, BMS has never communicated AWPs to the Publications. See Affidavit of Denise M. Kaszuba at ¶ 2, attached hereto as <u>Exhibit 3</u>. Since August 2001, BMS has reported to the Publications only a single list price to which it understands the Publications apply their own mark-up in determining the AWP they publish for BMS drugs. Id. In 2002 (the year the Together Rx program was established), First DataBank changed the mark up factor it used to determine AWP on BMS drugs to 25%. BMS did not request this change, did not provide any data to First DataBank to justify this change, and does not know why First DataBank made the change. Id.
- For all of its products, GSK reports only WAC to the Publications. See Affidavit of David A. Moules at ¶ 5, attached hereto as Exhibit 4. GSK does not report AWP to the Publications and has not done so since early 2001 (before the formation of Together Rx). Id. at ¶¶ 2, 5. Thus, since at least early 2001, the decision concerning what AWPs to publish for GSK products, and what ratios should be applied to WACs reported to the Publications by GSK to derive published AWPs, have been made by the Publications, and not by GSK. Id. at ¶11. In early January 2002, First DataBank changed the ratio between WAC and AWP on certain GSK drugs from 1.20 to 1.25. Id. at ¶ 7. GSK never suggested to First DataBank that it make such changes to the AWP of GSK drugs. Id. at ¶ 11. In fact, with respect to many GSK drugs, First DataBank is now publishing an AWP that is 1.25 times WAC, whereas Red Book is publishing an AWP that is 1.20 times WAC on the same drugs. Id.
- Janssen found AWPs listed for its drugs that were entirely contrary to the information it provided to the Publications. Janssen reports a direct distributor price and a suggested AWP to the Publications. See Affidavit of William Parks ("Parks Aff.") at ¶5, attached hereto as <u>Exhibit 5</u>. Prior to and after the inception of the Together Rx program in 2002,

Janssen reported suggested AWPs equal to 120% of its direct distributor prices. *Id.* at ¶ 6, 10. Red Book has published AWPs in accordance with Janssen's suggested AWP and continues to list an AWP that is 120% of Janssen's reported direct distributor prices. *Id.* at ¶ 9, 11. Beginning in 2002, however, First DataBank, contrary to Janssen's directions, began reporting AWPs that were 125% of Janssen's direct distributor prices. *Id.* at ¶ 6, 7. To date, despite Janssen's reporting suggested AWPs that are 120% of the direct distributor prices, and despite Red Book's publication of AWPs at the 120% level, First DataBank continues to list AWPs that are 125% of the reported direct distributor prices. *Id.* at ¶ 10, 11. *See also* Affidavit of Timothy B. Gribben of Ortho-McNeil Pharmaceutical, Inc., attached hereto as *Exhibit 7*.

• From March 2000 through August 2002, Novartis reported AWPs to the Publications that were 20 percent higher than WAC for the 20 Novartis drugs that are the subject of the AMCC. See Affidavit of Michael Conley at ¶¶ 3, 7, attached hereto as Exhibit 6. Until January 17, 2002, First Data Bank published AWPs for such drugs that were identical to the AWPs reported by Novartis. Id. at ¶ 10. In 2002, First Data Bank began publishing AWPs for 19 of the 20 Novartis drugs that were 25 percent higher than WAC, despite the fact that Novartis continued to report AWPs that were 20 percent higher than WAC. Id. at ¶ 11. Meanwhile, Red Book continued during this same period to publish AWPs as reported by Novartis (i.e., 20 percent higher than WAC) for these same drugs. Id. at ¶ 12.

In sum, the attached affidavits establish that the key allegation of conspiratorial conduct on the part of the Together Rx Defendants is simply wrong. Rather, it was the unilateral conduct of First DataBank that resulted in any uniform increase in the AWPs published by First DataBank, which is reflected in the chart that appears in the AMCC and the Proposed AMCC. Only the AWPs reported by First DataBank were at 25% above WAC, while the other major reporting publication listed AWPs of 20% above WAC, contrary to the alleged "conspiracy." This is not surprising, in light of the fact that First DataBank unilaterally adopted the higher mark-up, notwithstanding that it was given no direction to do so by the Together Rx Defendants and, in some instances, was given suggested AWPs that were only 20% above WAC. No amendment could cure this essential flaw in the plaintiffs' and the Proposed Intervenors' claims.

### **CONCLUSION**

For all the reasons stated above, and the reasons set forth in The Together Rx Defendants' Motion to Dismiss Counts V, VI, VII, VIII and X of the Amended Complaint, the Proposed Intervenors' Motion to Intervene should be denied.

Respectfully Submitted,

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February 19, 2004

### **CERTIFICATE OF SERVICE**

I certify that on February 19, 2004, a true and correct copy of the foregoing document was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to Verilaw Technologies for posting and notification to all parties.

Mary B. Marrane